

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1 Claim 1 (currently amended): A unit dosage form as an adjunct to biguanide or
2 sulfonyleurea therapy for supporting mitochondrial metabolism as a method for the prevention,
3 management and clinical amelioration of insulin resistance and type 2 diabetes and conditions
4 giving rise thereto, said unit dosage form comprising as active ingredients:

- 5 (a) L-carnitine,
- 6 (b) ascorbic acid,
- 7 (c) choline,
- 8 (d) ~~(e)~~ taurine,
- 9 (e) ~~(f)~~ folic acid, and
- 10 (f) ~~(g)~~ magnesium.

1 Claim 2 (original): A unit dosage form in accordance with claim 1 in which said
2 active ingredients are formulated as a substantially homogeneous tablet or capsule that releases
3 all of said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 3 (currently amended): A unit dosage form in accordance with claim 2 in
2 which:

- 3 (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
- 4 and
- 5 (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000
- 6 mg,
- 7 (c) said choline is in an amount ranging from about 15 mg to about 250 mg,
- 8 (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,
- 9 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,
- 10 and

11 (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 4-6 (canceled)

1 Claim 7 (original): A unit dosage form as an adjunct to biguanide or sulfonylurea
2 therapy specifically for nocturnal use as a method for the prevention, management and clinical
3 amelioration of insulin resistance and type 2 diabetes and conditions giving rise thereto, said unit
4 dosage form comprising as active ingredients:

- 5 (a) melatonin,
- 6 (b) L-carnitine,
- 7 (c) ubiquinone,
- 8 (d) folic acid,
- 9 (e) magnesium, and
- 10 (f) L-arginine.

1 Claim 8 (original): A unit dosage form in accordance with claim 7 in which said
2 active ingredients are formulated as a substantially homogeneous tablet or capsule that releases
3 all of said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 9 (original): A unit dosage form in accordance with claim 8 in which:
2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,
3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,
5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,
6 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,
7 and
8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1 Claim 10 (original): A unit dosage form for use as an adjunct to biguanide or
2 sulfonylurea therapy alternative to insulin for use as a method for the prevention, management

and clinical amelioration of insulin resistance and type 2 diabetes and conditions giving rise thereto, said unit dosage form comprising as active ingredients:

- (a) vanadium,
- (b) L-arginine,
- (c) chromium, and
- (d) zinc.

Claim 11 (original): A unit dosage form in accordance with claim 10 in which said active ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of said active ingredients into the stomach upon ingestion for contact with gastric fluid.

Claim 12 (original): A unit dosage form in accordance with claim 11 in which:

- (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,
- (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,
- (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,

and

- (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

Claim 13 (original): A unit dosage form in accordance with claim 1 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
L, carnitine	40-60%	balance
ascorbic acid	40-60%	balance
choline	100%	
folic acid	100%	
taurine	40-60%	balance

12 magnesium 40-60% balance

1 Claim 14 (canceled)

1 Claim 15 (original): A unit dosage form in accordance with claim 7 in which said
2 unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-
3 release layer, said active ingredients are distributed between said immediate-release layer and
4 said sustained-release layer in the following approximate proportions expressed as relative
5 weight percents:

	Immediate-Release Layer	Sustained-Release Layer
6 melatonin	40-60 %	balance
7 L-carnitine	40-60%	balance
8 zinc	40%-60%	balance
9 folic acid	100%	
10 magnesium	40-60%	balance
11 ubiquinone	100%	

1 Claim 16 (original): A unit dosage form in accordance with claim 10 in which
2 said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-
3 release layer, said active ingredients are distributed between said immediate-release layer and
4 said sustained-release layer in the following approximate proportions expressed as relative
5 weight percents:

	Immediate-Release Layer	Sustained-Release Layer
6 vanadium	40-60 %	balance
7 L-arginine	40-60%	balance
8 chromium	40%-60%	balance
9 zinc	40%-60%	balance

1 Claim 17 (canceled)

1 Claim 18 (currently amended): A unit dosage form in accordance with claims 4,
2 7 or 10 in which said L-arginine is in the form of a member selected from the group consisting of
3 L arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the
4 group consisting of Mg^{2+} and Zn^{2+} , bis-L arginine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L arginine or bis-L arginine, a metal ion selected
6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 19 (original): A unit dosage form in accordance with claims 1 or 7 in
2 which said L-carnitine is in the form of a member selected from the group consisting of L
3 carnitine ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the
4 group consisting of Mg^{2+} and Zn^{2+} , bis-L carnitine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L carnitine or bis-L carnitine, a metal ion selected
6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 20 (original): A unit dosage form in accordance with claim 1 in which said
2 L-taurine is in the form of a member selected from the group consisting of L taurine ascorbate,
3 bis-L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of Mg^{2+}
4 and Zn^{2+} , bis-L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} ,
5 and a complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of
6 Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate,
7 and ascorbate.

1 Claim 21 (original): A unit dosage form in accordance with claims 1 or 7 in
2 which said magnesium is in the form of a member selected from the group consisting of
3 magnesium, magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate,
4 magnesium α -lipoate, magnesium α -lipoate ascorbate and bis-ascorbate, magnesium taurate,
5 magnesium taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-

6 carnitate, magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and
7 magnesium bis-ascorbate.

1 Claim 22 (original): A unit dosage form in accordance with claim 10 in which
2 said zinc is in the form of a member selected from the group consisting of zinc halide, zinc
3 sulfate, zinc L-carnitate, zinc L-carnitate ascorbate and bis-ascorbate, zinc taurate, zinc taurine
4 ascorbate and bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-
5 carnitate, zinc L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc
6 ascorbate, and zinc bis-ascorbate.

1 Claim 23 (original): A unit dosage form in accordance with claim 10 in which
2 said vanadium is in the form of a member selected from the group consisting of vanadate,
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1 Claims 24-25 (canceled)

1 Claim 26 (original): A unit dosage form in accordance with claim 10 in which
2 said chromium is in the form of a member selected from the group consisting of chromium
3 dinicotinate, and chromium tripicolinate.

1 Claim 27 (currently amended): A method for treating a patient who is undergoing
2 biguanide therapy for the prevention, management, and clinical amelioration of insulin resistance
3 and type 2 diabetes and conditions giving rise thereto, to reduce undesirable physiological side
4 effects, and enhance the therapeutic effectiveness, of said biguanide therapy, said method
5 comprising administering to said patient a unit dosage form comprising as active ingredients:

- 6 (a) L-carnitine,
7 (b) ascorbic acid,
8 (c) choline,
9 (d) ~~(e)~~ taurine,
10 (e) ~~(f)~~ folic acid, and
11 (f) ~~(g)~~ magnesium.

1 Claim 28 (original): A method in accordance with claim 27 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 29 (currently amended): A method in accordance with claim 28 in which:
2 (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
3 and
4 (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000
5 mg,
6 (c) said choline is in an amount ranging from about 15 mg to about 250 mg,
7 (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,
8 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,
9 and
10 (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 30-32 (canceled)

1 Claim 33 (original): A method for treating a patient who is undergoing nocturnal
2 biguanide therapy for the preservation of plasma and mitochondrial membrane integrity for the
3 prevention, management, and clinical amelioration of insulin resistance and type 2 diabetes and
4 conditions giving rise thereto, to reduce undesirable physiological side effects, and enhance the
5 therapeutic effectiveness, of said biguanide therapy, said method comprising administering to
6 said patient a unit dosage form comprising as active ingredients:

- 7 (a) melatonin,
- 8 (b) L-Carnitine,
- 9 (c) ubiquinone,
- 10 (d) folic acid,
- 11 (e) magnesium, and
- 12 (f) L-arginine.

1 Claim 34 (original): A method in accordance with claim 33 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 35 (original): A method in accordance with claim 34 in which:
2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,
3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,
5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,
6 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,
7 and
8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1 Claim 36 (original): A method for treating a patient who is undergoing biguanide
2 therapy as an alternative to insulin for the prevention, management, and clinical amelioration of
3 insulin resistance and type 2 diabetes and conditions giving rise thereto, to reduce undesirable
4 physiological side effects, and enhance the therapeutic effectiveness, of said biguanide therapy,
5 said method comprising administering to said patient a unit dosage form comprising as active
6 ingredients:

7 (a) vanadium,
8 (b) L-arginine,
9 (c) chromium, and
10 (d) zinc.

1 Claim 37 (original): A method in accordance with claim 36 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 38 (original): A method in accordance with claim 37 in which:
2 (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,

(b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,

(c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,

and

(d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

Claim 39 (original): A method in accordance with claim 27 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
L, carnitine	40-60%	balance
ascorbic acid	40-60%	balance
choline	100%	
folic acid	100%	
taurine	40-60%	balance
magnesium	40-60%	balance

Claim 40 (canceled)

Claim 41 (original): A method in accordance with claim 33 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
melatonin	40-60 %	balance
L-carnitine	40-60%	balance
zinc	40%-60%	balance
folic acid	100%	

11	magnesium	40-60%	balance
12	ubiquinone	100%	

13 Claim 42 (original): A method in accordance with claim 36 in which said unit
14 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release
15 layer, said active ingredients are distributed between said immediate-release layer and said
16 sustained-release layer in the following approximate proportions expressed as relative weight
17 percents:

18		Immediate-Release Layer	Sustained-Release Layer
19	vanadium	40-60 %	balance
20	L-arginine	40-60%	balance
21	chromium	40%-60%	balance
22	zinc	40%-60%	balance

1 Claim 43 (canceled)

1 Claim 44 (currently amended): A method in accordance with claims ~~30~~, 33, or 36
2 in which said L-arginine is in the form of a member selected from the group consisting of L
3 arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the
4 group consisting of Mg^{2+} and Zn^{2+} , bis-L arginine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L arginine or bis-L arginine, a metal ion selected
6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 45 (original): A method in accordance with claims 27 or 33 in which said
2 L-carnitine is in the form of a member selected from the group consisting of L carnitine
3 ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group
4 consisting of Mg^{2+} and Zn^{2+} , bis-L carnitine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L carnitine or bis-L carnitine, a metal ion selected

6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 46 (original): A method in accordance with claim 27 in which said L-
2 taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-
3 L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and
4 Zn^{2+} , bis-L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and a
5 complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of Mg^{2+} and
6 Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate, and
7 ascorbate.

1 Claim 47 (original): A method in accordance with claims 27 or 33 in which said
2 magnesium is in the form of a member selected from the group consisting of magnesium,
3 magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium α -
4 lipoate, magnesium α -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium
5 taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitate,
6 magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-
7 ascorbate.

1 Claim 48 (original): A method in accordance with claim 36 in which said zinc is
2 in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-
3 carnitate, zinc L-carnitate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and
4 bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitate, zinc
5 L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc
6 bis-ascorbate.

1 Claim 49 (original): A method in accordance with claim 36 in which said
2 vanadium is in the form of a member selected from the group consisting of vanadate,
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1 Claim 50 (currently amended): A method in accordance with claim ~~claims 30 or~~
2 32 in which said D, α tocopherol is present in the form of a member selected from the group
3 consisting of D, α tocopherol succinate, D, α -tocopherol nicotinate, D, α -tocopherol picolinate,
4 D, α tocopherol acetate, and tocotrienol.

1 Claim 51 (currently amended): A method in accordance with claim ~~claims 40 or~~
2 50 in which said tocotrienol is present in the form of a member selected from the group
3 consisting of tocotrienol succinate, tocotrienol nicotinate, tocotrienol picolinate, and tocotrienol
4 acetate.

1 Claim 52 (original): A method in accordance with claim 36 in which said
2 chromium is in the form of a member selected from the group consisting of chromium
3 dinicotinate, and chromium tripicolinate.

1 Claim 53 (currently amended): A method for treating a patient who is undergoing
2 sulfonylurea therapy for the prevention, management, and clinical amelioration of insulin
3 resistance and type 2 diabetes and conditions giving rise thereto, to reduce undesirable
4 physiological side effects, and enhance the therapeutic effectiveness, of said sulfonylurea
5 therapy, said method comprising administering to said patient a unit dosage form comprising as
6 active ingredients:

- 7 (a) L-carnitine,
8 (b) Ascorbic acid,
9 (c) Choline,
10 (d) ~~(e)~~ Taurine,
11 (e) ~~(f)~~ Folic Acid, and
12 (f) ~~(g)~~ Magnesium.

1 Claim 54 (original): A method in accordance with claim 53 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 55 (currently amended): A method in accordance with claim 54 in which:

2 (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,

3 and

4 (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000

5 mg,

6 (c) said choline is in an amount ranging from about 15 mg to about 250 mg,

7 (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,

8 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,

9 and

10 (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 56-58 (canceled)

1 Claim 59 (original): A method for treating a patient who is undergoing nocturnal
2 sulfonylurea therapy for the preservation of plasma and mitochondrial membrane integrity for
3 the prevention, management, and clinical amelioration of insulin resistance and type 2 diabetes
4 and conditions giving rise thereto, to reduce undesirable physiological side effects, and enhance
5 the therapeutic effectiveness, of said sulfonylurea therapy, said method comprising administering
6 to said patient a unit dosage form comprising as active ingredients:

7 (a) melatonin,

8 (b) L-Carnitine,

9 (c) ubiquinone,

10 (d) folic acid,

11 (e) magnesium, and

12 (f) L-arginine.

1 Claim 60 (original): A method in accordance with claim 59 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 61 (original): A method in accordance with claim 60 in which:

- 2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,
3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,
5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,
6 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,
7 and
8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1 Claim 62 (original): A method for treating a patient who is undergoing
2 sulfonylurea therapy as an alternative to insulin for the prevention, management, and clinical
3 amelioration of insulin resistance and type 2 diabetes and conditions giving rise thereto, to
4 reduce undesirable physiological side effects, and enhance the therapeutic effectiveness, of said
5 sulfonylurea therapy, said method comprising administering to said patient a unit dosage form
6 comprising as active ingredients:

- 7 (a) vanadium,
8 (b) L-arginine,
9 (c) chromium, and
10 (d) zinc.

1 Claim 63 (original): A method in accordance with claim 62 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 64 (original): A method in accordance with claim 63 in which:

- 2 (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,
3 (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,
4 (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,

5 and

(d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

Claim 65 (original): A method in accordance with claim 53 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
L, carnitine	40-60%	balance
ascorbic acid	40-60%	balance
choline	100%	
folic acid	100%	
taurine	40-60%	balance
magnesium	40-60%	balance

Claim 66 (canceled)

Claim 67 (original): A method in accordance with claim 59 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
melatonin	40-60 %	balance
L-carnitine	40-60%	balance
zinc	40%-60%	balance
folic acid	100%	
magnesium	40-60%	balance
ubiquinone	100%	

Claim 68 (original): A method in accordance with claim 62 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
vanadium	40-60 %	balance
L-arginine	40-60%	balance
chromium	40%-60%	balance
zinc	40%-60%	balance

Claim 69 (canceled)

Claim 70 (currently amended): A method in accordance with claims 56, 59, or 62 in which said L-arginine is in the form of a member selected from the group consisting of L arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , bis-L arginine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and a complex of L arginine or bis-L arginine, a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate, and ascorbate.

Claim 71 (original): A method in accordance with claims 53 or 59 in which said L-carnitine is in the form of a member selected from the group consisting of L carnitine ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , bis-L carnitine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and a complex of L carnitine or bis-L carnitine, a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate, and ascorbate.

1 Claim 72 (original): A method in accordance with claim 53 in which said L-
2 taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-
3 L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and
4 Zn^{2+} , bis-L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and a
5 complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of Mg^{2+} and
6 Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate, and
7 ascorbate.

1 Claim 73 (original): A method in accordance with claims 53 or 59 in which said
2 magnesium is in the form of a member selected from the group consisting of magnesium,
3 magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium α -
4 lipoate, magnesium α -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium
5 taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitate,
6 magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-
7 ascorbate.

1 Claim 74 (original): A method in accordance with claim 62 in which said zinc is
2 in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-
3 carnitate, zinc L-carnitate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and
4 bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitate, zinc
5 L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc
6 bis-ascorbate.

1 Claim 75 (original): A method in accordance with claim 62 in which said
2 vanadium is in the form of a member selected from the group consisting of vanadate,
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1 Claims 76-77 (canceled)

1 Claim 78 ((original): A method in accordance with claim 36 in which said
2 chromium is in the form of a member selected from the group consisting of chromium
3 dinicotinate, and chromium tripicolinate.

1 Claim 79 (original): A method for treating a patient who is undergoing combined
2 biguanide and combined biguanide and sulfonylurea therapy for the prevention, management,
3 and clinical amelioration of insulin resistance and type 2 diabetes and conditions giving rise
4 thereto, to reduce undesirable physiological side effects, and enhance the therapeutic
5 effectiveness, of said combined biguanide and sulfonylurea therapy, said method comprising
6 administering to said patient a unit dosage form comprising as active ingredients:

- 7 (a) L-carnitine,
- 8 (b) ascorbic acid,
- 9 (c) choline,
- 10 (e) taurine,
- 11 (f) folic acid, and
- 12 (g) magnesium.

1 Claim 80 (original): A method in accordance with claim 79 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 81 (original): A method in accordance with claim 80 in which:

- 2 (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,
- 3 and
- 4 (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000
- 5 mg,
- 6 (c) said choline is in an amount ranging from about 15 mg to about 250 mg,
- 7 (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,

8 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,

9 and

10 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 82-84 (canceled)

1 Claim 85 (original): A method for treating a patient who is undergoing nocturnal
2 combined biguanide and sulfonylurea therapy for the preservation of plasma and mitochondrial
3 membrane integrity for the prevention, management, and clinical amelioration of insulin
4 resistance and type 2 diabetes and conditions giving rise thereto, to reduce undesirable
5 physiological side effects, and enhance the therapeutic effectiveness, of said combined biguanide
6 and sulfonylurea therapy, said method comprising administering to said patient a unit dosage
7 form comprising as active ingredients:

8 (a) melatonin,

9 (b) L-Carnitine,

10 (c) ubiquinone,

11 (d) folic acid,

12 (e) magnesium, and

13 (f) L-arginine.

1 Claim 86 (original): A method in accordance with claim 85 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 87 (original): A method in accordance with claim 86 in which:

2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,

3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,

4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,

5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,

6 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,

7 and

8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1 Claim 88 (original): A method for treating a patient who is undergoing combined
2 biguanide and sulfonylurea therapy as an alternative to insulin for the prevention, management,
3 and clinical amelioration of insulin resistance and type 2 diabetes and conditions giving rise
4 thereto, to reduce undesirable physiological side effects, and enhance the therapeutic
5 effectiveness, of said combined biguanide and sulfonylurea therapy, said method comprising
6 administering to said patient a unit dosage form comprising as active ingredients:

7 (a) vanadium,

8 (b) L-arginine,

9 (c) chromium, and

10 (d) zinc.

1 Claim 89 (original): A method in accordance with claim 88 in which said active
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 90 (original): A method in accordance with claim 89 in which:

2 (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,

3 (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,

4 (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,

5 and

6 (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

1 Claim 91 (original): A method in accordance with claim 89 in which said unit
2 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release
3 layer, said active ingredients are distributed between said immediate-release layer and said

sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
L, carnitine	40-60%	balance
ascorbic acid	40-60%	balance
choline	100%	
folic acid	100%	
taurine	40-60%	balance
magnesium	40-60%	balance

Claim 92 (canceled)

Claim 93 (original): A method in accordance with claim 85 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

	Immediate-Release Layer	Sustained-Release Layer
melatonin	40-60 %	balance
L-carnitine	40-60%	balance
zinc	40%-60%	balance
folic acid	100%	
magnesium	40-60%	balance
ubiquinone	100%	

Claim 94 (original): A method in accordance with claim 88 in which said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release layer, said active ingredients are distributed between said immediate-release layer and said sustained-release layer in the following approximate proportions expressed as relative weight percents:

		Immediate-Release Layer	Sustained-Release Layer
6			
7	vanadium	40-60 %	balance
8	L-arginine	40-60%	balance
9	chromium	40%-60%	balance
10	zinc	40%-60%	balance

1 Claim 95 (canceled)

1 Claim 96 (currently amended): A method in accordance with claims 82, 85, or 88
2 in which said L-arginine is in the form of a member selected from the group consisting of L
3 arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the
4 group consisting of Mg^{2+} and Zn^{2+} , bis-L arginine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L arginine or bis-L arginine, a metal ion selected
6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 97 (original): A method in accordance with claims 78 or 85 in which said
2 L-carnitine is in the form of a member selected from the group consisting of L carnitine
3 ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group
4 consisting of Mg^{2+} and Zn^{2+} , bis-L carnitine salt of a metal ion selected from the group
5 consisting of Mg^{2+} and Zn^{2+} , and a complex of L carnitine or bis-L carnitine, a metal ion selected
6 from the group consisting of Mg^{2+} and Zn^{2+} , and an anion selected from the group consisting of
7 hydroxide, halide, acetate, and ascorbate.

1 Claim 98 (original): A method in accordance with claim 78 in which said L-
2 taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-
3 L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and
4 Zn^{2+} , bis-L taurine salt of a metal ion selected from the group consisting of Mg^{2+} and Zn^{2+} , and a
5 complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of Mg^{2+} and

6 Zn^{2+} , and an anion selected from the group consisting of hydroxide, halide, acetate, and
7 ascorbate.

1 Claim 99 (original): A method in accordance with claims 79 or 85 in which said
2 magnesium is in the form of a member selected from the group consisting of magnesium,
3 magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium α -
4 lipoate, magnesium α -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium
5 taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitate,
6 magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-
7 ascorbate.

1 Claim 100 (original): A method in accordance with claim 88 in which said zinc is
2 in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-
3 carnitate, zinc L-carnitate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and
4 bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitate, zinc
5 L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc
6 bis-ascorbate.

1 Claim 101 (original): A method in accordance with claim 88 in which said
2 vanadium is in the form of a member selected from the group consisting of vanadate,
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1 Claims 102-103 (canceled)

1 Claim 104 (original): A method in accordance with claim 88 in which said
2 chromium is in the form of a member selected from the group consisting of chromium
3 dinicotinate, and chromium tripicolinate.